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| 10/681,002      | 10/08/2003  | Pierre-Etienne Chabrier De Lassauniere | 427.057-1           | 7432             |

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| EXAMINER |
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ANDERSON, REBECCA L

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1626

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 01/29/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/681,002

Applicant(s)

CHABRIER DE LASSAUNIERE ET AL.

Examiner

Rebecca L. Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2006 and 28 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 35,37-39,41,43 and 49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43 is/are rejected.
- 7) ☒ Claim(s) 35,37-39,41,43 and 49 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 10089993.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 35, 37-39, 41, 43 and 49 are currently pending in the instant application. Claim 43 is rejected and claims 35, 37-39, 41, 43 and 49 are objected. The previous office action had a typographical error the provisional obviousness type double patenting rejection. Specifically, the provisional obvious type double patenting rejection is over US Patent Application No. 10/333,556. Therefore, the instant action is a non-final action.

### ***Terminal Disclaimer***

The terminal disclaimer filed on 28 September 2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent Application No. 10/915001 and US Patent No. 6,586,454 has been reviewed and is accepted. The terminal disclaimer has been recorded. The terminal disclaimer has overcome the obvious type double patenting rejection of the claims over US Patent No. 6,586,454

### ***Response to Amendment and Arguments***

Applicant's amendment filed 7 November 2006 and applicants arguments filed 28 September 2006 have been fully considered and entered into the application. Applicants' amendment has overcome: the objection to claim 45 as containing non-elected subject matter; the objection to the Markush language of claims 40 and 42; has overcome the objection to claims 40, 42 and 48 as failing to further limit the parent claim; has overcome the objection to claims 43 and 45 for being dependent upon a cancelled claim; has overcome the objection to claims 38 and 39 as being substantial

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duplicates; has overcome the 35 USC 112 2<sup>nd</sup> paragraph rejection of claims 41, 45 and 47 for containing the term "general"; has overcome the 35 USC 112 2<sup>nd</sup> paragraph rejection of claim 35 for containing the term "comprising"; has overcome the provisional statutory double patenting rejection of claims 40, 42 and 48 over US Patent application 10/915001; has overcome the provisional obvious type double patenting rejection of claims 40, 42 and 48 over US Patent Application No. 10,333,556; has overcome the 35 USC 102(b) rejection of claims 35, 37, 45 and 46 as being anticipated by WO 98/58934; has overcome the 35 USC 102(e) rejection of claims 40 and 42 as being anticipated by WO 02/10140; and has overcome the 35 USC 103(a) rejection of claim 48 as being obvious over WO 02/10140.

Applicants' amendment and arguments have not overcome; the objection to claim 43 as failing to further limit the parent claim; has not overcome the provisional statutory double patenting rejection of claim 43 over US Patent Application no. 10/915,001; has not overcome the provisional obviousness type double patenting rejection of claim 43 over US Patent Application No. 10/333,556; and has not overcome the 35 USC 103(a) rejection of claim 43 as being obvious over WO 02/10140.

Applicants' claim 43 fails to limit the parent claim as claim 43 has the value of X as N wherein the value of X in the parent claim is S. Therefore the objection to claim 43 as failing to further limit the parent claim is maintained.

Applicant argues that the pharmaceutical composition of claim 43 is not the same pharmaceutical composition of claim 43 of US Patent Application no. 10/915,001, however, this argument is not persuasive as both the conflicting claim 43 and

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applicants' instant claim 43 are claiming a pharmaceutical composition of the compound butyl 2-(4-[1,1'-biphenyl]-4-yl-1H-imidazol-2-yl)ethylcarbamate or one of its pharmaceutically acceptable salts. Additionally, while applicant has filed a terminal disclaimer for 10/915,001, it is noted that a terminal disclaimer will not overcome a provisional statutory double patenting rejection. Therefore the provisional statutory double patenting rejection of claim 43 is maintained.

While applicant states that they have filed a terminal disclaimer for US Patent Application 10/333,556, it is noted that the terminal disclaimer filed 28 September does not include US Patent Application 10/333,556 and therefore the provisional obviousness type double patenting rejection of claim 43 is maintained.

Applicants' amendment has necessitated the following new rejections and objections: an objection to claim 35 as including the phrase "or alkyl" twice in the definition of R19, R20 and R21; an objection to claims 38 and 39 for failing to further limit the parent claim; a rejection to claim 43 for lacking antecedent basis; an objection to claim 39 as containing non-elected subject matter; and an objection to claims 37, 41 and 49 as being dependent upon an objected base claim.

### ***Claim Objections***

Claim 35 is objected to because of the following informalities: Specifically, claim 35 has "or alkyl" twice for the definition of R19, R20 and R21. Appropriate correction is required.

Claims 38, 39 and 43 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

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Specifically, claim 38 has the same definition for R1 and R2 as found in claim 35.

Claim 39 has a definition for R2 as alkyl which is not within the definition of R2 in claim 35. Claim 43 has a compound wherein X is N which is not within the definition of X in claim 35. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 39 is objected to as containing non-elected subject matter, specifically wherein R2 is alkyl. Claim 39 presented drawn solely to the elected invention would overcome this objection.

Claims 37, 41 and 49 are objected to as being dependent upon an objected base claim.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 43 recites the limitation "the active principle" in the pharmaceutical composition of claim 41. There is insufficient antecedent basis for this limitation in the claim as claim 41 does not include –an active principle–.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re*

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*Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 43 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 43 of copending Application No. 10/915001 (US Pre-grant publication 2005/0038087). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Specifically, the conflicting claims are claiming the exact same chemical species as applicants' instant claims.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 43 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 44 of copending Application No. 10/333,556. Although the conflicting claims are not identical, they are not patentably distinct from each other because conflicting claim 44 is claiming specific compounds which render obvious applicants' instantly claimed compounds such as butyl (4-(1,1'-biphenyl)-4-yl-1H-imidazol-2-yl)methylcarbamate and 4-(2-((1S)-1-((butoxycarbonyl)amino)ethyl)-1H-imidazol-4-yl)-1,1'-biphenyl. Furthermore, these compounds render obvious applicants' instantly claimed invention as to those skilled in chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. Also, the instant claimed compounds would have been obvious because one skilled in the art would have been



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motivated to prepare homologs of the compounds taught in the reference with the expectation of obtaining compounds which could be used in pharmaceutical compositions. Therefore, the instant claimed compounds would have been suggested to one skilled in the art. Lastly, nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. Since conflicting claim 44, renders obvious applicants' instant claimed invention as the conflicting claims are directed to specific compounds which render obvious applicants' instantly claimed product claims, applicants' product claims are therefore provisionally rejected on the ground of nonstatutory obviousness-type double patenting.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 43 is rejected under 35 U.S.C. 103(a) as being obvious over WO 02/10140.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer

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in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

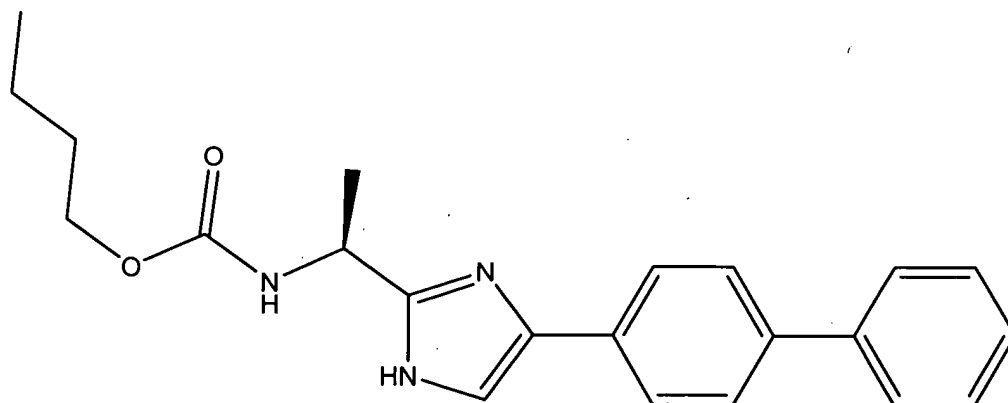
***Determining the scope and contents of the prior art***

WO 02/10140 discloses imidazolyl derivatives of the formula (I), page 2.

Pharmaceutical compositions are disclosed on page 20. Specific compounds which anticipate applicants' instant claims are found, for example, on page 327, 329, 333-339 and 341.

***Ascertaining the differences between the prior art and the claims at issue***

The difference between the prior art and the claims at issue is that the prior art claims are in a homologous series with the instant claimed compounds or are positional isomers of the instantly claimed compounds, see for example,



4-(2-((1S)-1-((butoxycarbonyl)amino)ethyl)-1H-imidazol-4-yl)-1,1'-biphenyl which differs

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only in the position of the (butoxycarbonyl)amino group on the ethyl at position 2 of the imidazolyl.

***Resolving the level of ordinary skill in the pertinent art***

However, minus a showing of unobvious results, it would have been obvious to one of ordinary skill in the art at the time of the invention when faced with the prior art of WO 02/10140, to prepare applicants' instantly claimed compounds which differ from the prior art compounds by only as a positional isomer. The motivation would be the expectation of preparing additional compounds useful as antagonists of somatostatin receptors and for inhibiting the proliferation of *Helicobacter pylori*. Furthermore, to those skilled in chemical art, nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, as taught by WO 02/10140 since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. In re Norris, 84 USPQ 458 (1950).

**Conclusion**

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Rebecca Anderson', is written over a horizontal line.

Rebecca Anderson  
Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600

22 January 2007